## REMARKS

**Status of Claims:**

Claims 1-27, 29, and 31 remain cancelled. Claims 46-66 and 68-69 remain withdrawn. Thus, claims 28, 30, 32-45, 67, and 70-78 are present for examination.

**Claim Rejection under 35 U.S.C. 112:**

The rejection under 35 U.S.C. 112, second paragraph, was addressed in the amendment and reply filed on October 3, 2005.

**Claim Rejection Under 35 U.S.C. 102:**

Claims 28, 30, and 32-41 are rejected under 35 U.S.C. 102(e) as being anticipated by Clark Jr. (U.S. Patent Number 6,343,225).

With respect to claims 28, 30, and 32-41, as amended, the rejection is respectfully traversed.

Independent claim 28, as amended, recites a sensor, comprising:

> "a sensor body having a space for receiving an active protein in a solidified form; and
>
> the active protein in said solidified form disposed within the space of the sensor body, the active protein in said solidified form comprising glucose oxidase, human serum albumin, and a cross-linking reagent, said active protein having been molded in a recess in a block of a mold and hardened into said solidified form prior to being disposed within the space of the sensor body, said active protein having been received within the space of the sensor body while in said solidified form;
>
> wherein said active protein in said solidified form is sufficiently immobilized prior to being disposed within the space of the sensor body such that the active protein in said solidified form minimizes swelling that would deform a shape of the sensor body and such that the active protein in said solidified form minimizes shrinkage that would create voids between the active protein in said

solidified form and the sensor body once the active protein in said solidified form has been received within the space of the sensor body." (Emphasis Added).

A sensor including the above-quoted features has at least the advantages that: (i) a sensor body has a space for receiving an active protein in a solidified form; (ii) the active protein in the solidified form is disposed within the space of the sensor body; and (iii) the active protein in the solidified form is sufficiently immobilized prior to being disposed within the space of the sensor body such that the active protein in the solidified form minimizes swelling that would deform a shape of the sensor body and such that the active protein in the solidified form minimizes shrinkage that would create voids between the active protein in the solidified form and the sensor body once the active protein in the solidified form has been received within the space of the sensor body. (Specification; page 1, lines 17-20; page 3, line 9 to page 4, line 23; page 5, line 2 to page 6, line 16; page 8, lines 14-17; page 9, lines 6-13; page 10, lines 18-22; page 19, lines 12-18; abstract; FIG. 7).

As explained in applicants' specification, previous processes for formulating an enzyme for use in a sensor involved placing the enzyme into a cavity within a sensing device while the enzyme was still in a liquid or gel-like form. In such processes, the gel-like enzyme would be placed into the sensing device cavity, where it would harden in place, within the cavity. (Specification; page 3, lines 9-12). Also, as explained in applicants' specification, enzymes produced by conventional processes can be susceptible to swelling or shrinking. (Specification; page 4, lines 5-6).

Applicants explained that sensor accuracy and sensitivity can be adversely affected when the enzyme utilized in the sensor is susceptible to leaching or swelling. Indeed, swelling of the enzyme over time can cause the sensor body to deform. Deformation of the body of the sensor may alter the response or the calibration of the sensor. Moreover, a swelling or leaching of the enzyme may cause the shape of the window in the sensing device to change which also could alter the response of the sensing device. (Specification; page 4, lines 11-16).

Also, applicants explained that, further problems have been associated with the process of injecting an enzyme into a sensing device while the enzyme is in a gel form. When an enzyme is injected into a cavity of a sensing device, it is difficult to ensure that the enzyme has filled the volume in the sensing device completely. If there are voids left in the cavity after the enzyme has been injected, those voids can adversely affect the stability and sensitivity of the sensing device. Moreover, since the enzyme may tend to shrink as it hardens or solidifies, further voids or spaces may be left in the enzyme cavity of the sensor. (Specification; page 4, lines 17-23).

Applicants' FIG. 7 shows two graphs illustrating the results of a swelling analysis. The first graph shows the swelling of a glucose oxidase-human serum albumin matrix formulated with insufficient immobilization. The second graph shows the swelling properties of the matrix formulated with improved immobilization according to embodiments of the present invention. (Specification; page 6, lines 12-16; page 8, lines 14-17; FIG. 7). As illustrated by the graphs of the results of the swelling analysis in FIG. 7, an active protein in solidified form in accordance with embodiments of the present invention may be sufficiently immobilized prior to being disposed within the space of a sensor body such that the active protein in the solidified form minimizes swelling that would deform a shape of the sensor body and such that the active protein in the solidified form minimizes shrinkage that would create voids between the active protein in the solidified form and the sensor body once the active protein in the solidified form has been received within the space of the sensor body. (FIG. 7).

Clark Jr. neither discloses nor suggests a sensor including the above-quoted features in which an active protein in solidified form is sufficiently immobilized prior to being disposed within a space of a sensor body such that the active protein in the solidified form minimizes swelling that would deform a shape of the sensor body and such that the active protein in the solidified form minimizes shrinkage that would create voids between the active protein in the solidified form and the sensor body once the active protein in the solidified form has been received within the space of the sensor body.

Indeed, Clark Jr. simply teaches the use of a gel. (Clark Jr.; abstract; column 9, lines 55-60). Clark Jr. does not even recognize the problems discussed at page 4 in applicants' specification and, as a consequence, Clark Jr. does not address such problems. Thus, Clark Jr. does not disclose or suggest an active protein in solidified form having the claimed characteristics. (Clark Jr.; abstract; column 9, lines 55-60).

Therefore, independent claim 28, as amended, is neither disclosed nor suggested by the Clark Jr. reference and, hence, is believed to be allowable. Because they depend from independent claim 28, dependent claims 30, 35, 38, and 41 are believed to be allowable for at least the same reasons that independent claim 28 is believed to be allowable.

Applicants express appreciation to the Examiner for the indication in the Interview Summary that, "embodiment of using a cross-linking reagent in vapor phase to further hardened the solidified form in the mold as shown by Fig 2b and as disclosed in the specification (pages 14 and 15) may be allowable in the absence of better prior art."

Claim 32 has been amended to be independent and recites the limitation, "wherein the active protein has been exposed to a vapor phase cross-linking process that employs said cross-linking reagent in a vapor phase." Therefore, independent claim 32, as amended, is neither disclosed nor suggested by the Clark Jr. reference and, hence, is believed to be allowable. Because they depend from independent claim 32, dependent claims 33-34, 36-37, and 39-40 are believed to be allowable for at least the same reasons that independent claim 32 is believed to be allowable.

**Claim Rejections Under 35 U.S.C. 103:**

Claims 42 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clark Jr.

Claims 44 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clark Jr. in view of Blubaugh Jr. et al. (U.S. Patent Number 5,964,993) (hereinafter Blubaugh Jr.).

Claim 67 is rejected under 35 U.S.C. 103(a) as being unpatentable over Clark Jr. in view of Liston et al. (U.S. Patent Number 4,891,104) (hereinafter Liston).

With respect to claims 42-45 and 67, as amended, the rejections are respectfully traversed.

Claims 42 and 43 depend from independent claim 28. As discussed above, independent claim 28, as amended, is neither disclosed nor suggested by the Clark Jr. reference. Therefore, dependent claims 42 and 43 are believed to be allowable for at least the same reasons that independent claim 28 is believed to be allowable. The Patent Office has not made out a *prima facie* case of obviousness under 35 U.S.C. 103(a).

Claims 44 and 45 depend from independent claim 28. As discussed above, independent claim 28, as amended, is neither disclosed nor suggested by the Clark Jr. reference. Moreover, Blubaugh Jr. does not cure the deficiency with respect to the teaching of Clark Jr. discussed above with regard to independent claim 28. Therefore, dependent claims 44 and 45 are neither disclosed nor suggested by the Clark Jr. and Blubaugh Jr. references and, hence, are believed to be allowable. The Patent Office has not made out a *prima facie* case of obviousness under 35 U.S.C. 103(a).

Claim 67 depends from independent claim 28. As discussed above, independent claim 28, as amended, is neither disclosed nor suggested by the Clark Jr. reference. Moreover, Liston does not cure the deficiency with respect to the teaching of Clark Jr. discussed above with regard to independent claim 28.

In particular, the bead in the system of Liston is not in solidified form. Liston teaches to compress the bead into a thin film by spreading the liquid across the limiting membrane 600. (Liston; FIG. 14; column 14, lines 38-46). The compression simply refers to squeezing the liquid to form a thin film of the liquid that is spread across the entire limiting membrane 600 (i.e. compressing the vertical dimension of the liquid into a thinner vertical dimension). (Liston; FIG.

14; column 14, lines 38-46). Liquids are very capable of being squeezed to be spread out on a surface when a compression force is applied as in the system of Liston. (Liston; FIG. 14; column 14, lines 38-46). However, a solidified mass would not spread out across a membrane when compressed, but would likely break apart due to the compression force. Thus, Liston teaches away from the bead being in solidified form by teaching that the bead is compressed on the limiting membrane 600 to form a thin film.

Therefore, dependent claim 67 is neither disclosed nor suggested by the Clark Jr. and Liston references and, hence, is believed to be allowable. The Patent Office has not made out a *prima facie* case of obviousness under 35 U.S.C. 103(a).

Claims 70-78 recite features that are not found in the Clark Jr., Liston, and Blubaugh Jr. references and, hence, are believed to be allowable.

**Conclusion:**

Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 50-0872. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 50-0872.

If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 50-0872.

Respectfully submitted,

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By Just Soloja #56,252 for/

FOLEY & LARDNER LLP
Customer Number: 23392
Telephone: (310) 975-7963
Facsimile: (310) 557-8475

Ted R. Rittmaster
Attorney for Applicant
Registration No. 32,933